

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 00D-1629]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidances for Industry on "Effectiveness of Anthelmintics: Specific Recommendations for Feline" (VICH GL20), and "Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus gallus" (VICH GL21); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two final guidances for industry (Nos. 113 and 114, respectively) entitled "Effectiveness of Anthelmintics: Specific Recommendations for Feline" (VICH GL20), and "Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus gallus" (VICH GL21). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the final guidances to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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Submit written comments on the final guidance documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance documents.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical recommendations for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health, Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese

Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** of December 18, 2000 (65 FR 79113), FDA published the notice of availability of these VICH draft guidances, giving interested persons until January 17, 2001, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidances for industry, VICH GL20 and VICH GL21.

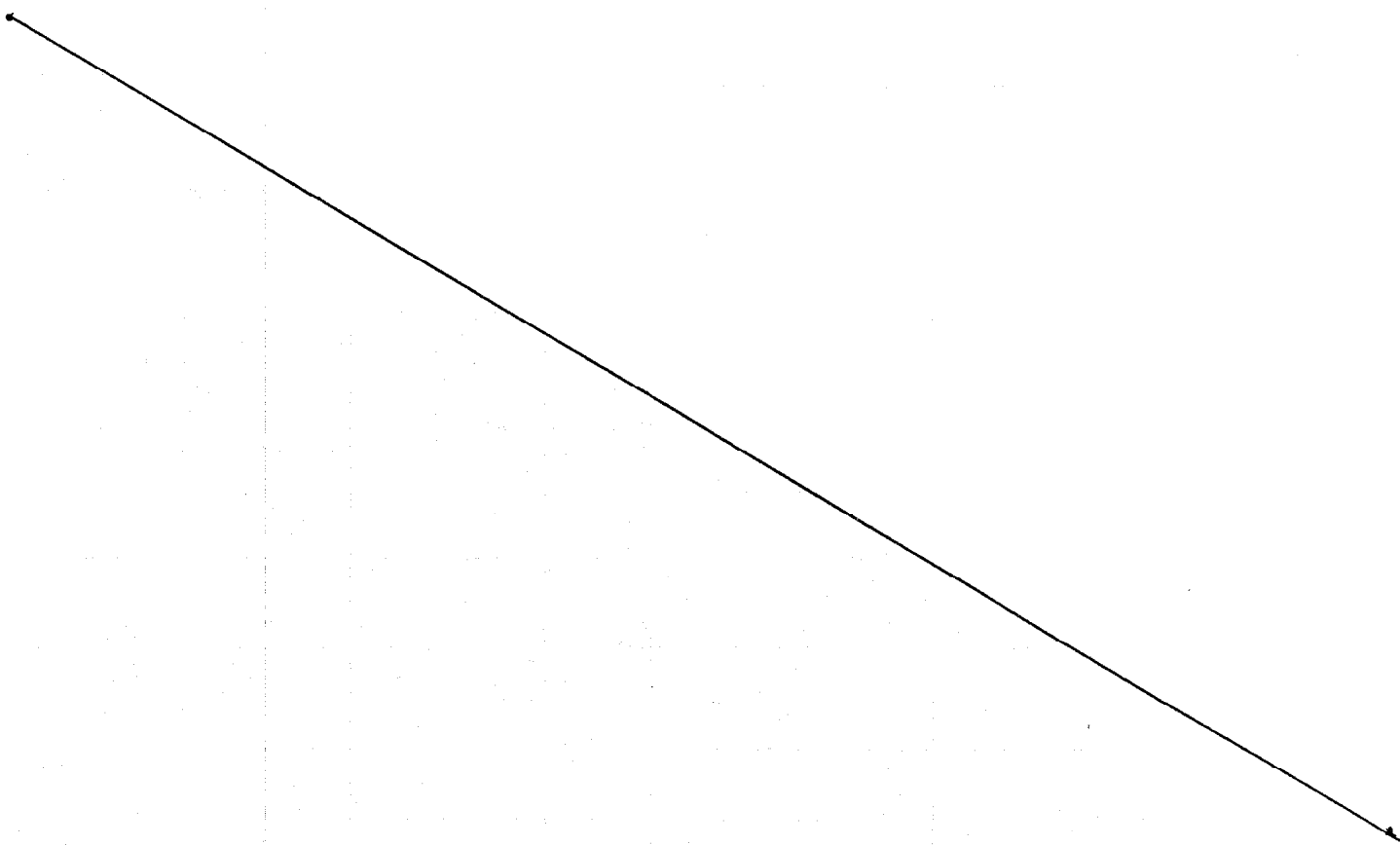
These final guidances, VICH GL20 and VICH GL21, should be read in conjunction with the "Effectiveness of Anthelmintics: General Recommendations (EAGR)" which was published in the **Federal Register** of April 6, 2001 (66 FR 18257). The guidances for feline and poultry are part of the EAGR, and the aim of these final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities with the EAGR.

The final level 1 guidance documents, developed under the VICH process, are consistent with FDA's good guidance practices regulation (21 CFR 10.115). These documents do not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations. Information collected is covered under OMB control number 0910-0032.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

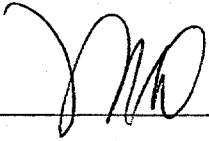
Interested persons may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding these guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. The guidances and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

Persons with access to the internet may obtain the documents at <http://www.fda.gov/cvm>.

Dated: 6/17/02
June 17, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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